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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,198	04/04/2005	Yoko Matsuzawa	040894-7204	9611

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WASHINGTON, DC 20004

EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,198	MATSUZAWA ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response of 12/12/06 is acknowledged. The 5/3/06 claim amendments have been entered as requested (see New Matter rejection below), and the claims examined based on these amendments. The indication of Allowable Subject Matter has been VACATED. The present action is being sent NON-FINAL in order to clarify the issues and raise new issues, which have been realized upon further review. Claims 1-13 are examined on the merits.

Information Disclosure Statement

The information disclosure statement filed 4/4/05 includes only a translation of the abstract of JP 11-322787 (now JP-B-3012932 Patent), which Applicant's own specification (page 1-2) cites as teaching the compound/product of the invention. Upon reconsideration of the amended subject matter and further review of the specification, the above JP patent is deemed to either teach or render obvious (alone or with 2nd references) the claims of the present invention, absent clear evidence to the contrary. The above patent is deemed to be the equivalent of Kogiso et al. (US 6,136,956, issued 10/24/00), and the latter specification is relied upon for the teachings of both. Should this not be so, Applicant is requested to file the full translation of this application/Patent in support of any evidence to the contrary, and point out any discrepancies there between. This Examiner finds it more than a little unclear why Applicant did not disclose Applicant's own '956 patent (very similar to the present application and the English equivalent patent to Applicant's untranslated JP '932) - either via specification background or IDS, as relevant information to the present application?

Acknowledgement of Related PCT Search Report

The search report for related PCT/JP03/12636, and the 4 “A” references cited therein is acknowledged. It is noted that the JP International Authority (IA) did not cite JP 11-322787 (now JP-B-3012932 Patent), which Applicant’s own specification (page 1-2) cites as teaching the compound/product of the invention. Notwithstanding the results of the JP IA’s findings, each application and set of claims are analyzed on their own merits, by each respective country/IA. Currently, this IA and Examiner’s findings are not the same as those of the JP IA.

Claim Rejections - 35 USC § 112 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant indicated in the 5/3/06 response that “[c]laim 1 was also amended to add further clarity and to add that “when R is a hydrogen atom, m is not 1.” No new matter has been added by the amendments.” Applicant has provided no specification pages where support for such an amendment may be found. In a review of the originally filed 14 page specification and claims, support could not be found for a) “m is not 1”, or the combination of b) “when R is a hydrogen atom, me is not 1”. It appears Applicant filed these amendments to get around the

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102(e) reference to Hotta et al. (US 6,489,265 B1); however, unless support for such an amendment is shown, Applicant must amend the claims as previously presented.

Products of (& processes of making) the Invention

The present invention, as best as can be determined by the claim language and brief specification, takes the formula 1 FIBER products patented in parent '265 (see Fig. 2 therein) and now pursues the SPHERICAL products/particles/microcapsules comprising the same formula 1 (see present applications Fig's 2-3). The issue is whether it would have been obvious to one of ordinary skill in the art at the time of the invention to use the formula 1 compound to create spherical versions of the assertedly more difficult to construct and earlier patented elongated fiber versions (Applicant's words in his earlier '265 patent, col. 1, lines 21-34)? Upon reconsideration, and absent evidence to the contrary, this Examiner now believes so.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by either Kogiso et al. (US 6,136,956, issued 10/24/00, two inventors in common with the present application) or

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Agency of Ind. Science & Techn. (now JP-B-3012932 Patent, 12/17/99, application JP 11-322787, cited in IDS of 4/4/05) - both discussed collectively under Kogiso et al.

It is noted that Applicant's earliest effective priority date is 10/7/02, greater than one year after the '956 patent issued.

Kogiso et al. teach:

1) the identical compound of formula I (entire document). As the present specification page 1-2 recites: "[i]t is described, for example, in Japanese Patent No. 3012932 and Chem. Comm., 1998, pp. 1791-1792 that the above compound forms a nano-scale fiber having a width of about 10 to 30 nm when an aqueous alkaline solution of the compound is gradually acidified"]].

Kogiso et al. ;

2) linear products, namely fibers and fibrous assemblies, comprising the same; as well as spherical products, the easier to make product as discussed (col. 1, lines 21-34); and

3) a method of making the same using a substrate having hydrophilicity (e.g. glass vial), alkali metal salt, precipitated under a weakly acid atmosphere (Example 1; col. 2, lines 21-31; claims 5-7).

Specifically, the background on the art's processing of the easier made fine spherical versions of the '956 patented fibers/fibrous assemblies of Kogiso et al. is described in Kogiso et al. at col. 1, lines 21-34 and col. 3, lines 29-53:

"...well known, fibrous assemblies of a peptide lipid are widely employed in many applications, besides the applications as a drug delivery system or an adsorbent, in the fields of medical and pharmaceutical sciences as a bioadaptable material, in the fields of electronic and information-processing technologies as a material of microelectronic parts, in the fields of food industries, agriculture, forestry and fiber industries as an emulsifying agent, stabilizer, dispersing agent or moisturizing agent and so on.

In the prior art, spherical assemblies obtained from a natural phospholipid or so-called liposomes are known among molecular aggregates formed from a phospholipid. Such a

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spherical assembly is usually prepared by the thin-film method, thermal dispersion method, cholic acid method or reversed-layer evaporation method (see, for example, "Seitaimaku Jikkenhou" (Experimental Methods for Biomembranes), volume 2, page 185, published by Kyoritu Shuppan Co.).

Each of these prior art methods, however, requires extremely high skillfulness. In addition, the *molecular aggregates* obtained by these methods are limited to a *monolayered vesicle* or *spherical multilayered vesicle* and long fibrous assemblies cannot be prepared thereby. On the other hand, several methods are disclosed, for example, in Journal of the American Chemical Society, volume 119, pages 9120-9124 (1997) for the preparation of a fibrous assembly from a synthetic amphiphilic compound in water. Each of these methods, however, is a method in which fibrous assemblies are obtained by spontaneous *precipitation* or crystallization from a hot concentrated *aqueous solution* containing an *amphiphilic compound* so that the yield of the product is necessarily limited.

[]

The various reagents, i.e. amino group-protective agent, carboxyl group-protective agent and coupling agent, and the procedures in the above described reaction can be conventional and freely selected from those used in the prior art for peptide synthesis. The intermediate peptide compounds formed in the course of the reaction can readily be isolated and purified by washing the reaction mixture with an acid or alkali aqueous solution followed by recrystallization or reprecipitation.

[]

The fine fibrous assembly of the invention is obtained from an aqueous solution of an alkali metal salt of the above described bola-form peptide lipid compound by causing precipitation thereof in a crystalline form.

The only thing Kogiso et al. does not expressly teach is that said fine spherical products have "uniform molecular orientation" or the word "microcapsule" (and that said microcapsule can encompass a substance having hydrophilicity, e.g. glass?). Hence the present rejection is made under 103, rather than 102, as expressly anticipated.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a "uniformly oriented" and/or "microcapsule" spherical version of the fiber/fibrous assemblies comprising compounds of formula 1 in Kogiso et al., because Applicant's earlier work expressly states that making the spherical versions of such constructs is easier and known.

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It was the linear, fiber versions that posed enablement issues. Spherical constructs are well known in the art to have uniform molecular orientation and be used in the biomedical fields as microcapsules, which encapsulate water-attracted compounds/molecules. No secondary references to the same needed or further expounding necessary, as evident by the recited specification pages above, from Kogiso et al.

Thus, from the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The generally amorphously claimed products of claims 1-13 provide no substantive structural attributes, beyond the known core compound formula I, as to the “fine spherical particles” of the present invention. Thus, any general description of a spherical product as discussed in Kogiso et al. or the art generally, is deemed to satisfy this limitation, absent evidence to the contrary.

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Additionally, claims 1-13 provide no substantive structural attributes, beyond the known core compound formula I, as to the “uniform molecular orientation” of the particles. Thus, it is not understood what the structure of a product/particle is as to “uniform molecular orientation”, other than the inherent “uniform molecular orientation” already known to exist in spherical products known in the art, absent evidence to the contrary.

As to claims 4-13, what is meant by “immersing a substrate having hydrophilicity in an aqueous solution”? Is this substrate e.g. glass as claimed in claim 6? What is the role of said substrate in forming the spherical particle? Does it have to be a specific shape to form said particle? Under the broadest reasonable interpretation of the claims, the glass vial surrounding the aqueous solution in which formula 1 is contained, could meet the limitation of being the water-attracted substrate.

Additionally, in claims 8-13, what is the hydrophilic core “substance” (as opposed to “substrate”) that is supposed to be encapsulated inside the formula 1 spherical body? Glass? Plastic? Certain water attracted pharmaceutical compounds? Such has not been distinctly claimed and it is uncertain whether any organic or inorganic compound is contemplated or capable of being housed therein. Absent evidence to the contrary any compound that does not repel water is deemed to satisfy this limitation.

Conclusion

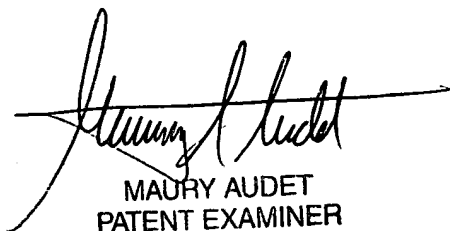
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 08/15/2007



MAURY AUDET
PATENT EXAMINER